PTO/SB/21 (09-06)

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## **TRANSMITTAL FORM**

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Total Number of Pages in This Submission

Application Number 10/594,990 Filing Date September 29, 2006 First Named Inventor Manuel WORCEL Art Unit N/A Examiner Name Not Yet Assigned Attorney Docket Number 0102258.00375US2

	ENCLOSURES (Check all that apply)							
Amendment  After F	ittal Form ttached //Reply	Drawing(s)  Licensing-related Papers  Petition  Petition to Convert to a Provisional Application  Power of Attorney, Revocation	After Allowance Communication to TC  Appeal Communication to Board of Appeals and Interferences  Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)  Proprietary Information  Status Letter					
Express Aba	ssing Parts/	Change of Correspondence Address  Terminal Disclaimer  Request for Refund  CD, Number of CD(s)  Landscape Table on CD  Remarks	Other Enclosure(s) (please Identify below):					
L] 37 CFI	to Missing Parts under R 1.52 or 1.53 SIGNATU	JRE OF APPLICANT, ATTORNEY, O	R AGENT					
Firm Name	WILMER CUTLER F	PICKERING HALE AND DORR LL	Ρ					
Signature Printed name	Beliefa L	en -						
	Belinda Lew							
Date	JANUARY	29,2007 Reg. No	53,212					



Docket No.: 0102258.00375US2

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Manuel WORCEL

Confirmation No.:

(a)(a)(a)

Application No.:

10/594,990

Art Unit:

N/A

Filed:

September 29, 2006

Examiner:

Not Yet Assigned

Title:

METHOD FOR TREATING BLOOD DISORDERS WITH NITRIC

OXIDE DONOR COMPOUNDS

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT (IDS)

Dear Sir:

This Information Disclosure Statement is being filed prior to the mailing date of a first Office Action on the merits. No fee is required.

Applicants request that the Examiner initial and return a copy of the enclosed Form PTO SB-08 with the next communication.

Respectfully submitted,

Dated: JANUARY 29, 2007

Registration No.: 53,212

Wilmer Cutler Pickering Hale and Dorr LLP 1875 Pennsylvania Avenue, NW Washington, DC 20006 (202) 663-6000 (telephone) (202) 663-6363 (facsimile)

PTO/SB/08A/B (09-06)

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Sub	ostitute for form 1449/PTO			Complete if Known		
				Application Number	10/594,990	
11	NFORMATIO!	N DI	SCLOSURE	Filing Date	September 29, 2006	
S	TATEMENT	BY A	APPLICANT	First Named Inventor	Manuel WORCEL	
				Art Unit	N/A	
	(Use as many sheets as necessary)			Examiner Name	Not Yet Assigned	
Sheet	1	of	2	Attorney Docket Number	0102258.00375US2	

	U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
l	AA*	US-20060182815-A1	08-17-2006	Gladwin et al.		

	FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	ВА	WO-2005/004884-A2	01-20-2005	M. Gladwin			
	ВВ	WO-2005/007173-A1	01-27-2005	M. Gladwin			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. \*Applicant's unique citation designation number (optional). \*See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspio.gov/">www.uspio.gov/</a> or MPEP 901.04. \*Inter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Skind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \*Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	CA	Bryan et al. "Nitrite is a signaling molecule and regulator of gene expression in mammalian tissues" Nature Chemical Biology, Advanced Online Publication, pages 1-8 (2005).	
	СВ	Cosby et al. "Nitrite reduction to nitric oxide by deoxyhemoglobin vasodilates the human circulation" Nature Medicine, Vol. 9, No. 12, pages 1498-1505 (2003).	
	CC	Dejam et al. "Emerging role of nitrite in human biology" Blood Cells, Molecules, and Diseases, Vol. 32, pages 423-429 (2004).	
	CD	Diaz et al. "Effect of graded levels of dietary nitrite on pulmonary hypertension in broiler chickens and dilatory cardiomyopathy in turkey poults" Avian Pathology, Vol. 24, pages 109-120 (1995).	
	CE	Doyle et al. "Kinetics and Mechanism of the Oxidation of Human Deoxyhemoglobin by Nitrites" The Journal of Biological Chemistry, Vol. 236, No. 23, pages 12393-12396 (1981).	
	CF	Duranski et al. "Cytoprotective effects of nitrite during in vivo ischemia-reperfusion of the heart and liver" The Journal of Clinical Investigation, pages 1-9 (2005).	
	CG	Gabel et al. "Decreased intracellular pH is not due to increased H+ extrusion in preconditioned rat hearts" Am. J. Physiol. Vol. 273, pages H2257-H2262 (1997).	
	СН	Gladwin et al. "Haldane, hot dogs, halitosis, and hypoxic vasodilation: the emerging biology of the nitrite anion" J. Clin. Invest., Vol. 113, pages 19-21 (2004).	
	CI	Gladwin et al. "Role of circulating nitrite and S-nitrosohemoglobin in the regulation of regional blood flow in humans" Vol. 97, No. 21, pages 11482-11487 (2000).	
	CJ	Gruetter et al. "Methylene blue inhibits coronary arterial relaxation and guanylate cyclase activation by nitroglycerin, sodium nitrite, and amyl nitrite <sup>1</sup> " Cancer J. Physiol. Pharmacol., Vol. 59, pages 150-156 (1981).	
	CK	Hunter et al. "Inhaled nebulized nitrite is a hypoxia-sensitive NO-dependent selective pulmonary vasodilator" Nature Medicine, Vol. 10, No. 10, pages 1122-1127 (2004).	
	CL	Johnson et al. "Cardioprotective Effects of Acidified Sodium Nitrite in Myocardial Ischemia with	

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Signature	Considered		

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_	stitute for form 1449/PTO			Complete if Known		
				Application Number	10/594,990	
IN	<b>IFORMATION</b>	I DI	SCLOSURE	Filing Date	September 29, 2006	
s	TATEMENT E	3Y /	APPLICANT	First Named Inventor	Manuel WORCEL	
				Art Unit	N/A	
	(Use as many sheets as necessary)			Examiner Name	Not Yet Assigned	
Sheet	2	of	2	Attorney Docket Number	0102258.00375US2	

	Reperfusion" The Journal of Pharamacology and Experimental Therapeutics" Vol. 252, No. 1, pages 35-41 (1989).	
СМ	Johnson et al. "Cardioprotective effects of authentic nitric oxide in myocardial ischemia with reperfusion" Critical Care Medicine, Vol. 19, No. 2, pages 244-251 (1991).	
CN	Kelm et al. "Serum nitrite sensitively reflects endothelial NO formation in human forearm vasculature: evidence for biochemical assessment of the endothelial L-arginine-NO pathway" Cardiovascular Research, Vol. 4, pages 765-772 (1999).	
СО	Lauer et al. "Plasma nitrite rather than nitriate reflects regional endothelial nitric oxide synthase activity but lacks intrinsic vasodilator action" PNAS, Vol. 98, No. 22, pages 12814-12819 (2001).	
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CQ	Lundberg et al. "NO Generation From Nitrite and Its Role in Vascular Control" Arterioscler Thromb Vasc Biol., Vol. 25, pages 915-922 (2005).	
CR	Modin et al. "Nitrite-derived nitric oxide: a possible mediator of 'acidic-metabolic' vasodilation" Acta Physiol Scand, Vol. 171, pages 9-16 (2001).	
CS	Moulds et al. "A Comparison of the Effects of Hydrallazine, Diazoxide, Sodium Nitrite and Sodium Nitroprusside on Human Isolated Arteries and Veins" J. Clin. Pharmac., Vol. 1, pages 57-61 (1981).	
СТ	Pluta et al. "Nitrite Infusions to Prevent Delayed Cerebral Vasospasm in a Primate Model of Subarachnoid Hemorrhage" JAMA, Vol. 293, No. 12, pages 1477-1484 (2005).	
CU	Rassaf et al. "Evidence for in vivo transport of bioactive nitric oxide in human plasma" The Journal of Clinical Investigation, Vol. 109, No. 9, pages 1241-1248 (2002).	
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CW	Shen et al. "Effects of EGb 761 on nitric oxide and oxygen free radicals, myocardial dmaage and arrhythmia in ischemia-reperfusion injury in vivo" Biochimica et Biophysica Acta 1406, pages 228-236 (1998).	
СХ	Shirasaki et al. "Endothelium removal augments vasodilation by sodium nitroprusside and sodium nitrite" European Jouranl of Pharmacology, Vol. 114, pages 93-96 (1985).	
CY	Tiravanti et al. "Nitrosyl-Heme Complexes Are Formed in the Ischemic Heart", The Journal of Biological Chemistry, Vol. 279, No. 12, pages 11065-11073 (2004).	
CZ	Uchida et al. "Nitric Oxide Donating Compounds Inhibit HC1-Induced Gastric Mucosal Lesions Mainly via Prostaglandin" Jpn. J. Pharmacol., Vol. 85, pages 133-138 (2001).	
CA1	Wanstall et al. "Responses to vasodilator drugs on pulmonary artery preparations from pulmonary hypertensive rats" Br. J. Pharmacol., Vol. 105, pages 152-158 (1992).	
CB1	Webb et al. "Inorganic Nitrite: Portector Against Ischaemia Reperfusion INjury in the Heart?"  Br. J. Pharmacol. (2003)	
CC1	Webb et al. "Reduction of nitrite to nitric oxide during ischemia protects against myocardial ischemia-reperfusion damage" PNAS, Vol. 101, No. 37, pages 13683-13688 (2004).	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date
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<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.